

Remarks

After amendment, claims 1-45 are pending in the present application. The amendment to the claims has been made primarily to address the Examiner's 35 U.S.C. §112, second paragraph rejection of the originally filed claims. Support for the amendment to the claims may be found throughout the original specification and claims. No new matter has been added to the present application by presentation of this amendment.

The courtesy of Examiner Krass extending Applicants and the undersigned attorney an invitation to interview the present application on February 20, 1997 in light of his busy schedule is respectfully acknowledged. The amended claims reflect the discussions with Examiner Krass and the agreement which was reached with the Examiner at the February 20, 1997 interview.

The Examiner has rejected 1-35 on the basis that certain terms are indefinite under 35 U.S.C. §112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. The Examiner has also rejected claims 1-35 variously under 35 U.S.C. §§102(b) and 103. Applicants shall address each of the Examiner's rejections in the sections which follow.

The §112, Second Paragraph Rejection

The Examiner has rejected claims 1-35 for a variety of reasons set forth in his **Indefinite**

M19-032.020
Amendment/Response
March 31, 1997

A

Rejection of the December 30, 1996 office action. In order to address the Examiner's rejection, Applicant's have simply followed the Examiner's suggestions and amended the claims accordingly.

With respect to the indefiniteness of the term "substantially non-crosslinked", it is respectfully submitted that this term has obtained a definiteness in the art. However, in order to advance the prosecution of the present application and without impacting the scope of the claims, Applicants have amended the claims to insert the amount of crosslinking to which this term generally corresponds. It is respectfully submitted that this term should not be construed as limiting the scope of the present invention as this term may be construed to determine potential equivalents of the present invention.

With respect to the term "poly(oxyethylene) rich", Applicants have amended the claims to remove this term from the claims. Nonetheless, it is respectfully submitted that the claims which now recite the use of chains which comprise poly(oxyethylene) are, at least, similar in scope to the claims which were rejected for the use of the indefinite term.

Correspondingly, it is respectfully submitted that the claims are now in compliance with the provisions of 35 U.S.C. §112.

The §102 Rejection

The Examiner has rejected claims 1-35 as being anticipated under 35 U.S.C. §102(b) by Cohn, et al., U.S. Patent No. 4,826,945 ("Cohn"). Separately, the Examiner has rejected claims 1-10 as being anticipated under 35 U.S.C. §102(b) by Casey, et al., U.S. Patent No. 4,452,973 ("Casey"). Applicants respectfully traverse the Examiner's rejection.

The present invention as set forth in the 45 claims of the present application relates to methods for reducing or preventing adhesions utilizing certain compositions comprising poly(hydroxy-carboxylic acid)/poly(oxyalkylene) ABA triblocks which have an EO/LA ratio ranging from about 0.5 to about 5.0. It has been discovered by Applicants that the use of these polymers provide unexpectedly favorable properties for reducing and/or eliminating adhesions.

Cohn does not anticipate the present invention. Cohn clearly did not recognize the present invention inasmuch as the uses which are disclosed in Cohn do not have any relationship to reducing or eliminating adhesion, for example, after a surgery. The uses to which the Cohn polymers are taught relate to sutures and other structures which have no relationship or relevance to the reduction or prevention of adhesion. In particular, the teachings of Cohn actually emphasize structures which would promote tissue binding, quite the opposite of the present invention. Inasmuch as Cohn does not mention or suggest adhesion, it is respectfully submitted that Cohn does not anticipate the present invention.

Regarding the Examiner's contention that Cohn somehow anticipates the present invention under the doctrine of inherent anticipation, it is respectfully submitted that in order to anticipate the present invention under the doctrine of inherency, there must be a teaching in the reference which always, necessarily and invariably produces the claimed invention. In Cohn, there is no teaching that would satisfy this criteria for establishing a cogent case of inherent anticipation. Moreover, it is not even clear that the teachings of Cohn would ever produce a result which could be construed as an inherent anticipation. It is respectfully submitted that the Cohn reference does not impact the patentability of the present invention.

Turning to the Examiner's argument that Casey anticipates the present invention, it is respectfully submitted that Casey is inapposite. Casey relates to certain ABA triblocks which are not chain extended and which are completely distinguishable from the polymeric compositions which are used in the present inventive methods. In addition, Casey does not even relate to the reduction or prevention of adhesion. The polymers of Casey, with their emphasis on structural integrity, are not useful in the present invention. Consequently, it is submitted that Casey is non-anticipatory and actually, a somewhat irrelevant reference.

It is respectfully submitted that the Examiner has not made out a cogent case that the present invention is anticipation by the art. Applicants respectfully submit that the present invention is in compliance with the requirements of 35 U.S.C. §102.

The Rejection Under 35 U.S.C. §103

The Examiner has rejected claims 1-35 under 35 U.S.C. §103(a) as being obvious over Sheffield, et al. ("Sheffield"), in view of Cohn. The Examiner also rejects claims 1-10 of the present invention under 35 U.S.C. §103(a) as being obvious over Sheffield in view of Casey. For the following reasons, Applicants respectfully submit that the Examiner has not made out a cogent case that the present invention is obvious over the cited references.

The Examiner cites Sheffield as teaching the use of polylactide copolymers, in gel form, as carriers for NSAIDs to be used in the inhibition of postsurgical adhesions. The teachings of Cohn are cited for teaching ABA block copolymers which are related to the chemical compositions which are used in the present methods. The Examiner agrees that Cohn does not teach the use of those polymers in a method according to the present invention.

The present invention has been described above and is referenced here. Sheffield relates to the use of polymeric compositions, in particular, polylactic acid polymers which are used to deliver pharmaceutical compositions which have pharmacological anti-adhesion type activity. There is absolutely no disclosure or suggestion of the present invention in Sheffield. To the extent that Sheffield teaches anything, it is that any polymer which is to be used to treat adhesion must separately contain a pharmacologically active agent which has anti-adhesion activity. Sheffield clearly did not recognize that the polymer itself could desirably be instilled with anti-

adhesion characteristics. In the present invention, it is the claimed polymeric compositions which contain ABA triblocks and contain poly(oxyalkylene) chains as claimed which advantageously may be employed to reduce or eliminate adhesion. Sheffield does not disclose polymers which relate to the present invention, nor does this reference even recognize the desirability of instilling the polymer itself with chemical characteristics which would reduce or eliminate adhesion.

According to Sheffield, any biodegradable polymer may be used to deliver the requisite biological agents, provided that the chemistry is compatible with that delivery. Sheffield provides absolutely no suggestion or motivation of the present invention. The teaching of Sheffield is clearly deficient and does not render the present invention obvious.

Cohn does not cure the fatal deficiencies of Sheffield. As the Examiner has noted, Cohn clearly does not teach the use of the disclosed polymers to eliminate or reduce adhesion. Nor does Cohn emphasize the specific polymeric compositions which find use in the methods of the present invention. Without providing a cure for the inadequate teachings of Cohn, it is respectfully submitted that Cohn does not bolster the Examiner's arguments in any way. Consequently, it is respectfully submitted that the present invention is clearly patentable over Sheffield, in view of Cohn.

The Examiner has also rejected claims 1-10 as being obvious over Sheffield, in view of Casey. A description of the present invention and the teachings of Sheffield are referenced here. Casey does absolutely nothing to cure the inadequacies of Sheffield, which have been detailed

hereinabove. Casey relates to polymeric compositions which are not the presently claimed compositions which find use in the method of the present invention. Moreover, there is no teaching in Casey whatsoever about the use of any polymers disclosed therein to reduce or eliminate adhesion. In reality, Casey actually teaches away from the present invention because Casey emphasizes polymers which contain high percentages by weight of polylactic acid and limits the amount of poly(oxyethylene) in his ABA triblocks. In doing so, Casey is actually deemphasizing or teaching away from one of the features of the present invention, ~~that~~ the amount of poly(oxyethylene) in the compositions which are used in the present methods, is an important feature. Consequently, the Examiner's arguments that the present invention is obvious over the teachings of Sheffield, in view of Casey, is simply not tenable. It is respectfully submitted that the art of record provides absolutely no teaching or suggestion of the desirability of using the claimed polymeric compositions to reduce or eliminate adhesions.

For all of the above reasons, Applicants respectfully assert that the claims set forth in the amendment to the application of the present invention are now in compliance with 35 U.S.C. Applicants respectfully submit that the present application is now in condition for allowance and such action is earnestly solicited.

Applicants have added one independent claim and nine dependent claims. A fee in the amount of \$139.00 is due for the presentation of this amendment. In addition, Applicants enclose a supplemental information disclosure statement and a check in the amount of \$230.00 for the

presentation of the supplemental information disclosure statement. A total fee in the amount of \$369.00 is enclosed. A verified statement claiming small entity status has been filed in this application.

Please charge any additional fee or credit any overpayment to Deposit Account No. 13-0025.

Respectfully submitted,

McAulay Fisher Nissen Goldberg & Kiel

By: 

Henry D. Coleman

Regis. No. 32,559

261 Madison Avenue

New York, New York 10016

I hereby certify that this correspondence is being deposited with the U.S. Postal Office as first class mail in an envelope addressed to: Assistant Commissioner of Patents, Washington, D.C., 20231 on March 31, 1997.


Ruth Montalvo